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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,041	12/22/2006	Soili Peltonen	0365-0670PUS1	4395
2292 7590 06/08/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
CHAN, HENG M				
ART UNIT		PAPER NUMBER		
1795				
NOTIFICATION DATE		DELIVERY MODE		
06/08/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/573,041

Applicant(s)

PELTONEN ET AL.

Examiner

HENG M. CHAN

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-63 is/are pending in the application.
4a) Of the above claim(s) 56-63 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 31-55 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Applicant's amendments and remarks filed 3/1/2010 have been acknowledged. Claims 1-30 have been canceled. New claims 31-63 are pending. Please note errors in the status of the claims in the remarks that new claims 31-55, not 31-56, are process claims that correspond to the elected Group I and new claims 56 and 57 (i.e. product claims of Group II) and claims 58-62 (i.e. product claims of Group III) are product claims that correspond to the non-elected groups. Newly submitted claim 63 that is directed to a product comprising the pigment or filler product (Group V) replaces the non-elected Group IV (i.e. use of a pigment or a filler product). The inventions listed as Groups I-III and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A review of US 6,780,820 to Bobsein makes clear that the inventions of the groups I-III and V lack the same or corresponding special technical feature because the cited reference(s) teaches a thermosensitive recording material comprising a layer comprising multivoided polymeric particles, i.e. a nanoporous, coral-like material, of from 0.1 micron to 2 micron, and polymeric binders such as methacrylamide copolymer starch and derivatives thereof (column 1, lines 9-26 and 56-59; column 2, lines 53-57). Accordingly, the prior art of the record supports restriction of the claimed subject matter in to the groups as mentioned immediately above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The previous objections to the claims and specification and claim rejections under 35 USC 112, 2nd paragraph and 103(a) have been withdrawn as a result of Applicants' amendments. The following new claim objections and grounds of rejections are being made in view of Applicants' amendments to the claims.

Claim Objections

2. Claims 33 and 34 are objected to because "the concentration of the solution" should be changed to "the concentration of the starch derivative of the solution" in order to be consistent with claim 1 and [0052] of the PG-Pub of the instant application.

Claims 44-46 and 53-55 are duplicate claims. Cancellation or amendment of at least one of the duplicate claims is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31, 36, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites that the solution of starch derivative and a mixture of a solvent and water is brought into contact with a non-solvent. However, the fate of the non-solvent thereafter is unclear. The non-solvent should be a component in the dispersion which is formed from the solvent and the water and the liquid phase comprising both the solvent and the water. It is unclear if the non-solvent is separated from the precipitate just like the water. For examination purposes, the non-solvent is treated as a component in both the dispersion and the liquid phase and is removed from the precipitate.

Claim 36 recites "the temperature" in line 2. It is unclear what the temperature is. For examination purposes, the instant claim is considered to recite that the starch derivative has a glass transition point of at least 100°C.

Claim 49 recites "fine particles" in line 1. It is unclear what the fine particles are. For examination purposes, the instant claim is read as written.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 31-40, 42-48, and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,562,459 to Bengs et al. In view of US 6,617,449 to Tanaka.**

Regarding claims 31, 36, and 37, Bengs et al. teach a method of manufacturing a starch-based material, comprising:

dissolving a starch derivative, e.g. a starch ester, in a solvent or a mixture of a solvent and aqueous solutions (column 5, lines 13-25),

bringing the solution into contact with a precipitant or a non-solvent in which the starch derivative is not dissolved so as to precipitate the starch derivative from a dispersion which is formed from the solvent, the water, and the non-solvent, so that a precipitate comprising the starch derivative and a liquid phase comprising both the solvent, the water, and the non-solvent are formed, and

removing the precipitate from the liquid phase (Claim 1; abstract; column 3, lines 6-24 and 38-42; column 5, lines 13-25 and 33-37; Example 1).

Bengs et al. do not expressly teach that the starch derivative has a glass transition point of 60°C to 350° as per claim 31 or at least 100°C as per claim 36.

Tanaka also relates to biodegradable starch esters made from esterified or acylated starch compounds and teaches that the starch esters have a glass transition point by differential thermal analysis (JIS K 7121: referred to hereinafter as "glass transition point") of 140°C or less, preferably 130°C or less. The lower limit of the glass transition point shall be usually 80°C, preferably 100°C (column 2, lines 52-56).

It would have been obvious to one of ordinary skill in the art at time of invention to have recognized that the starch esters of Bengs et al. have the claimed glass transition point because Tanaka shows that starch esters have glass transition points that are overlapping with the claimed ranges. A *prima facie* case of obviousness exists

in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Bengs et al. also do not expressly teach removing the solvent from the liquid phase and separating and recovering the precipitate from the water and the non-solvent.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have separated the precipitate from the liquid phase in a batch manner or continuously, because the court held the claimed continuous operation would have been obvious in light of the batch process of the prior art and so that the reverse must be true. See MPEP 2144.04. Also, changing the order of steps in a process does not impart patentability in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results). See MPEP § 2144.04. Furthermore, "the starch-based pigment or filler" is a recitation of an intended use of the claimed invention in the preamble. It must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP § 2111.02.

Regarding claim 32, Bengs et al. teach rapidly dissolving 1g of starch in 5ml of the solvent in Example 1b, which suggests that no excess solvent or just enough solvent is used to dissolve the starch derivative.

Regarding claims 33 and 34, Bengs et al. teach that the total concentration of the starch derivative in the solvent may vary within wide limits according to demand. It is preferably in a range from 0.02 g (starch derivative)/ml (solvent) to 1.0 g/ml, in particular from 0.05 g/ml to 0.8 g/ml and particularly preferably from 0.3 g/l to 0.6 g/l (column 5, lines 26-32). Bengs et al. teach adding 30 g of starch to 500 ml of solvent, which would be about 22 wt.% (Example 1).

Bengs et al. do not expressly teach that the concentration of the starch derivative in the solution is at least 1% by weight, preferably approximately 10-30% by weight.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have varied the concentration of the starch derivative in the solution according to demand as suggested by Bengs et al. and optimized the concentration through routine experimentation. A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claim 35, Bengs et al. teach a concentration of starch that is overlapping with the claimed ranges of concentrations (see rejections of claims 33 and 34 above).

Bengs et al. do not expressly teach that the viscosity of the solution is 1-5 times the viscosity of water.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have realized that the viscosity of a starch solution depends on the

concentration of the starch and because Beng et al. teach an overlapping range of concentration of starch in the solution, the viscosity of the same solution necessarily follows the concentration. Therefore, the viscosity of the solution of Beng et al. is expected to overlap with the claimed range.

Regarding claims 38 and 39, Bengs et al. teach that the starch derivative can be chemically modified, for example, by esterification and/or etherification. "Measures for such modification are well known to the skilled worker." (column 3, lines 38-42).

Bengs et al. do not expressly teach that that the starch ester is an ester formed of starch and C1-4 alkane acid as per claim 38 or that the starch ester is a starch acetate as per claim 39.

Tanaka teaches that the starch ester can esterified or acylated by replacing hydrogens in reactive hydroxyl groups with, for example, C₂₋₄ short-chain acyl groups (abstract). A C₂ acyl group would give a starch acetate.

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have used a starch acetate as a starch derivative in the method of Bengs et al., motivated by the fact that Bengs et al. encourage the skilled artisan to use known methods of esterification, such as acylation demonstrated by Tanaka, to derive the desired starch ester for the method.

Regarding claim 40, Bengs et al. teach that the starch can be chemically modified by esterification and/or etherification of a hydroxyl group (column 3, lines 38-42). That is, the starch ester can also be hydroxyl alkylated.

Regarding claim 42, Bengs et al. teach that the precipitate is separated from the liquid phase.

Bengs et al. do not expressly teach that after the solvent is removed, the precipitate separated from the liquid phase does not contain such amount of solvent residues that the solvent can be detected with a 300 MHz NMR device.

However, absent of such a specific teaching about the amount of solvent residues would clearly suggest to one of ordinary skill in the art at time of invention that there was not any residual solvent in the precipitate separated from the liquid phase. Furthermore, the skilled artisan would have not expected any residual solvent after extensive purification and drying as described in Example 1.

Regarding claim 43, based on the examples of solvents and precipitants or non-solvents (column 5, lines 13-25 and 33-37), the solvent can be completely mixed with the non-solvent. For example, a mixture of DMSO and water (solvent) is miscible with water (non-solvent).

Regarding claims 44-46 and 53-55, Bengs et al. teach that the solvent/precipitant(non-solvent) ratio is preferably selected within a range from 1:1000 to 1:4 (part of solvent/parts of precipitant) preferably 1:100 to 1:10 and in particular 1:70 to 1:30 (column 5, lines 38-41). The ratio is usually based on mass. A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claims 47 and 52, Bengs et al. teach introducing the solution into the precipitant with rapid mixing, or stirring, i.e. in a turbulent condition, to form spherical microparticles (abstract; column 5, lines 47-51; Example 1b).

Regarding claim 48, Bengs et al. teach that the particles may have average diameters (number average) of from 1 nm to 100 μm , preferably 100 nm to 10 μm and particularly preferably 1 μm to 5 μm (column 7, lines 38-41). A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art". *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

Regarding claims 50 and 51, Bengs et al. teach that the order in which the starch derivative solution and the precipitate or non-solvent are combined, for example whether the precipitant is added to the solvent or vice versa, is unimportant in this context (column 5, lines 48-51).

Bengs et al. do not expressly teach that the solution is added, while mixing, to the non-solvent so as to produce a coral-like, porous pigment with the claimed particle size and pore size.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have obtained the claimed coral-like, porous pigment with the claimed particle size and pore size in the method of Bengs et al. when the solution is added to the non-solvent with stirring, because the skilled artisan would have expected the same

product from the same method, in light of the obvious modifications to the method of claim 31 as explained above and absent convincing evidence to the contrary.

5. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengs et al. and Tanaka as applied to claim 31 above, in view of US 4,011,392 to Rudolph et al.

Regarding claim 41, Bengs et al. do not expressly teach that the degree of substitution of the ester groups of an ester functioning as the starch derivative is chosen in a way that the starch derivative is fundamentally insoluble in the non-solvent.

However, Rudolph et al., who also relate to starch esters, teach that the degree of substitution is a critical factor in determining the starch esters characteristics and performance. In general, the hydrophobicity of the starch polymer increase substantially as the degree of substitution increases. This may be illustrated by the solubility properties of the starch polymer which changes from water-soluble, organic-insoluble at low degrees of substitution to water-insoluble, organic-soluble at high degrees of substitution (column 5, lines 11-19).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have appropriately chosen a degree of substitution for the starch esters so that the starch derivative is substantially insoluble in the non-solvent, in the method provided by Bengs et al., motivated by the fact that the skilled artisan would have appreciated making the starch derivative insoluble in the non-solvent in order for it to be

precipitated and the skilled artisan would have done so by manipulating the degree of substitution of starch esters as suggested by Rudolph et al.

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bengs et al. and Tanaka as applied to claim 47 above, in view of US 4,716,186 to Portnoy et al.

Regarding claim 17, Bengs et al. teach that the starch derivative is precipitated with a precipitate or non-solvent, separated, and recovered (Example 1).

Bengs et al. do not expressly teach that fine particles dispersed in the liquid phase are precipitated by salting out after the starch derivative is precipitated from the solution.

Portnoy et al. also relate to starch derivatives and teach that the starch derivative can be separated from impurities such as inorganic salts by for example, salting out (column 1, lines 51-63).

Therefore, it would have been obvious to one of ordinary skill in the art at time of invention to have further precipitated fine particles from the liquid phase after separating the starch derivative in the method provided by Bengs et al., motivated by the fact that the skilled artisan would have appreciated further extract the starch derivative from the liquid phase and possible getting rid of impurities as suggested by Portnoy et al.

Response to Arguments

7. Applicant's arguments with respect to claims 31-55 have been considered but are moot in view of the new ground(s) of rejection.

Applicants have amended the new independent claim 31 to recite that the starch derivative has a glass transition point of 60°C to 350°C. The Examiner has responded by combining Bengs with Tanaka to address the glass transition point of starch esters. Applicants also argued that water is employed as a non-solvent and the starch derivative is dissolved in a mixture of the solvent and water. The Examiner has pointed out the specific teaching of Bengs where the solvent may be a mixture of solvent and water and the non-solvent may be water (column 5, lines 13-25 and 33-37).

Applicants argued about considerable advantages due to the claimed starch derivatives and the water non-solvent of the claimed invention. However, since Bengs teach using the same starch derivatives in light of Tanaka and the same non-solvent, the claimed features and the advantageous properties discussed in Applicants' remarks would necessarily follow the method. This provides the rationale and reasonable expectation of success based on the combination of Bengs and Tanaka.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HENG M. CHAN whose telephone number is (571)270-5859. The examiner can normally be reached on Monday to Friday, 9:00 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer K. Michener can be reached on (571)272-1424. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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